

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings of claims in the application.

In the Claims

Claim 1 (Previously presented): A method for treating hyperplasia of non-cancerous cells in a blood vessel of a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

Claim 2 (Cancelled)

Claim 3 (Original): A method according to claim 1 wherein said hyperplasia occurs in blood vessel neointima.

Claim 4 (Original): A method according to claim 1 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

Claim 5 (Original): A method according to claim 4 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

Claim 6 (Original): A method according to claim 1 wherein said composition is administered systemically.

Claim 7 (Original): A method according to claim 6 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

Claim 8 (Original): A method according to claim 1 wherein said composition is administered before, during or after the occurrence of said hyperplasia.

Claim 9 (Previously presented): A method for reducing neointimal hyperplasia of non-cancerous cells associated with vascular interventional procedure(s) in a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising at least one amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

Claim 10 (Original): A method according to claim 9 wherein said procedure comprises angioplasty, stenting or atherectomy.

Claim 11 (Original): A method according to claim 9 wherein said composition is administered before, during or after the vascular interventional procedure.

Claim 12 (Original): A method according to claim 9 wherein said composition is administered at the time of the vascular interventional procedure.

Claim 13 (Original): A method according to claim 9 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

Claim 14 (Original): A method according to claim 13 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

Claim 15 (Original): A method according to claim 9 wherein said composition is administered systemically.

Claim 16 (Original): A method according to claim 9 wherein said composition is administered by deployment of a stent containing said at least one drug coated thereon.

Claim 17 (Previously presented): A method to reduce proliferation and cell migration in a subject undergoing a vascular interventional procedure, said method comprising systemically administering to said subject before, during or after said procedure, a formulation comprising (i) an amorphous drug in nanoparticle form, wherein said drug inhibits proliferation and cell migration,

and (ii) a biocompatible protein, wherein said drug is coated with a coating consisting essentially of said protein, and wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

Claims 18-30 (Cancelled)

Claim 31 (Previously presented): The method according to claim 1, wherein said drug is a taxane or analog or homolog thereof.

Claim 32 (Previously presented): The method according to claim 31, wherein said drug is a taxane.

Claim 33 (Previously presented): The method according to claim 32, wherein said taxane is paclitaxel.

Claim 34 (Previously presented): The method according to claim 1, wherein said drug is an epothilone or an analog or homolog thereof.

Claim 35 (Previously presented): The method according to claim 34, wherein said drug is an epothilone.

Claim 36 (Previously presented): The method according to claim 1, wherein said drug is a rapamycin or analog or homolog thereof.

Claim 37 (Previously presented): The method according to claim 36, wherein said drug is a rapamycin.

Claim 38 (Previously presented): The method according to claim 1, wherein said protein is albumin.

Claim 39 (Previously presented): The method according to claim 9, wherein said drug is a taxane or analog or homolog thereof.

Claim 40 (Previously presented): The method according to claim 39, wherein said drug is a taxane.

Claim 41 (Previously presented): The method according to claim 40, wherein said taxane is paclitaxel.

Claim 42 (Previously presented): The method according to claim 9, wherein said drug is an epothilone or an analog or homolog thereof.

Claim 43 (Previously presented): The method according to claim 42, wherein said drug is an epothilone.

Claim 44 (Previously presented): The method according to claim 9, wherein said drug is a rapamycin or analog or homolog thereof.

Claim 45 (Previously presented): The method according to claim 44, wherein said drug is a rapamycin.

Claim 46 (Previously presented): The method according to claim 9, wherein said protein is albumin.

Claim 47 (Previously presented): The method according to claim 17, wherein said drug is a taxane or analog or homolog thereof.

Claim 48 (Previously presented): The method according to claim 47, wherein said drug is a taxane.

Claim 49 (Previously presented): The method according to claim 48, wherein said taxane is paclitaxel.

Claim 50 (Previously presented): The method according to claim 17, wherein said drug is an epothilone or an analog or homolog thereof.

Claim 51 (Previously presented): The method according to claim 50, wherein said drug is an epothilone.

Claim 52 (Previously presented): The method according to claim 17, wherein said drug is a rapamycin or analog or homolog thereof.

Claim 53 (Previously presented): The method according to claim 52, wherein said drug is a rapamycin.

Claim 54 (Previously presented): The method according to claim 17, wherein said protein is albumin.

Claim 55 (Previously presented): The method according to claim 17, wherein said procedure comprises angioplasty, stenting or atherectomy.

Claim 56 (Previously presented): The method according to claim 1 wherein said composition is administered by deployment of a stent containing at least one drug coated thereon.

Claim 57 (Previously presented): The method according to claim 1 wherein said nanoparticles do not have a polymeric core matrix.

Claim 58 (Previously presented): The method according to claim 1 or 57 wherein the average diameter of the nanoparticles in the composition is no greater than about 200 nm.

Claim 59 (Previously presented): The method according to claim 38 wherein said albumin is human serum albumin.

Claim 60 (Previously presented): The method according to claim 9 wherein said nanoparticles do not have a polymeric core matrix.

Claim 61 (Previously presented): The method according to claim 9 or 60 wherein the average diameter of the nanoparticles in the composition is no greater than about 200 nm.

Claim 62 (Previously presented): The method according to claim 15 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

Claim 63 (Previously presented): The method according to claim 46 wherein said albumin is human serum albumin.

Claim 64 (Previously presented): The method according to claim 17 wherein said procedure comprises angioplasty, stenting or atherectomy.

Claim 65 (Previously presented): The method according to claim 17 wherein said composition is administered before, during or after the vascular interventional procedure.

Claim 66 (Previously presented): The method according to claim 17 wherein said composition is administered at the time of the vascular interventional procedure.

Claim 67 (Previously presented): The method according to claim 17 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

Claim 68 (Previously presented): The method according to claim 67 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

Claim 69 (Previously presented): The method according to claim 17 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

Claim 70 (Previously presented): The method according to claim 17 wherein said nanoparticles do not have a polymeric core matrix.

Claim 71 (Previously presented): The method according to claim 17 or 70 wherein the average diameter of the nanoparticles in the composition is no greater than about 200 nm.

Claim 72 (Previously presented): The method according to claim 54 wherein said albumin is human serum albumin.

Claim 73 (Previously presented): The method according to any one of claims 7, 62, and 69, wherein said composition is administered intra-arterially.

Claim 74 (Previously presented): The method according to claim 73 wherein said composition is administered to a coronary artery.

Claim 75 (Previously presented): The method according to claim 73 wherein said composition is administered to a femoral artery.

Claim 76 (Previously presented): The method according to claim 73 wherein said composition is administered to a carotid artery.

Claim 77 (Previously presented): The method according to any one of claims 1, 9, and 17, wherein said composition is administered in conjunction with a device for delivery of a pharmacological agent.

Claim 78 (Previously presented): The method according to claim 77 wherein said device is a balloon catheter.